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HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Legislative proposal on health technology assessment

On 24 March 2021, the EU Member States agreed to begin negotiations with the European Parliament concerning a legislative proposal on health technology assessment. Health technology includes medicinal products, medical devices or medical and surgical procedures, as well as measures for disease prevention, diagnosis or treatment used in healthcare.

There had been no significant developments in this process for around three years, given the lack of consensus among Member States on the content of the document.

In particular, the legislative proposal includes the creation of a coordination group comprising the national health authorities of the various Member States and the work of groups will essentially involve clinical assessment and joint scientific consultation on health technologies.

The legislative proposal under discussion should benefit patients, as well as the Member States and the companies and other bodies that make health technologies available on the market. It should also facilitate patient access to these health technologies and enable more comprehensive scientific information to be made available to national health authorities.

The proposal will also reduce the bureaucracy of procedures associated with the process of companies placing health technologies on the market and making them available. In particular, it will relieve companies of the burden of having to make information on health technologies available at national level when it has already been made available centrally to the EU. This simplification will make it possible to optimise resources and avoid the duplication of procedures.

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The aim of the health technology assessment process is to enable the competent authorities of each Member State to assess the relative effectiveness of new or existing health technologies on the market. Its main focus is on the added value of the health technology compared to other new or existing health technologies on the market. This assessment is essential to enable Member States to make informed decisions on various issues, such as pricing or co-payment of health technologies.

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